



THE UNIVERSITY *of* EDINBURGH

Edinburgh Research Explorer

Independent endpoint event review for the elimination of reporting bias in an open label phase III pharmaceutical trial

Citation for published version:

Hall, P, Waterhouse, A, Smith, I, Brown, J, Gregory, W, Steger, G, Bell, R & Cameron, D 2015, 'Independent endpoint event review for the elimination of reporting bias in an open label phase III pharmaceutical trial', *Trials*, vol. 16, no. Suppl 2, pp. P188. <https://doi.org/10.1186/1745-6215-16-S2-P188>

Digital Object Identifier (DOI):

[10.1186/1745-6215-16-S2-P188](https://doi.org/10.1186/1745-6215-16-S2-P188)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Publisher's PDF, also known as Version of record

Published In:

Trials

Publisher Rights Statement:

© 2015 Hall et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated

General rights

Copyright for the publications made accessible via the Edinburgh Research Explorer is retained by the author(s) and / or other copyright owners and it is a condition of accessing these publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy

The University of Edinburgh has made every reasonable effort to ensure that Edinburgh Research Explorer content complies with UK legislation. If you believe that the public display of this file breaches copyright please contact openaccess@ed.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.



POSTER PRESENTATION

Open Access

Independent endpoint event review for the elimination of reporting bias in an open label phase III pharmaceutical trial

Peter Hall^{1,2*}, Anna Waterhouse², Isabelle Smith², Julia Brown², Walter Gregory², Guenther Steger⁴, Richard Bell³, David Cameron¹

From 3rd International Clinical Trials Methodology Conference
Glasgow, UK. 16-17 November 2015

Background

Open label randomised controlled trials may be subject to bias where outcome ascertainment relies on treating clinician decisions. In the setting of a multinational randomised controlled open label phase three pharmaceutical trial we implemented a rigorous verification algorithm to mitigate against such bias. We report the impact of the algorithm's application on the primary endpoint.

Method

The BEATRICE trial recruited 2591 patients with early surgically treated triple negative breast cancer from 360 sites in 37 countries into a two way randomisation. The primary endpoint was investigator reported invasive disease free survival (IDFS). A novel rigorous 103-step endpoint review algorithm was developed to provide central ratification in support of, but not mandating locally reported events.

Results

IDFS events were reported in 393 patients. There was no statistically significant difference between the arms. The HR was 0.88 [95% CI 0.72-1.07] prior to algorithm application compared with 0.87 [95% CI 0.72-1.07]. 393 events, the algorithm input changed dates in 74 (19%), type of event in 7 (2%) and site of event in 11 (3%). The event number did not change.

Conclusion

Reassuringly the primary results of this open label RCT did not change with enhanced independent interrogation

and review of reported endpoints. Current standard trial reporting procedures appear to be adequate even in the open label setting.

Authors' details

¹University of Edinburgh, Edinburgh, UK. ²University of Leeds, Leeds, UK. ³Andrew Love Cancer Centre, Victoria, Australia. ⁴Medical University of Vienna, Vienna, Austria.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P188

Cite this article as: Hall et al.: Independent endpoint event review for the elimination of reporting bias in an open label phase III pharmaceutical trial. *Trials* 2015 **16**(Suppl 2):P188.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit



¹University of Edinburgh, Edinburgh, UK
Full list of author information is available at the end of the article